

Food and Drug Administration, HHS

§21.51

manual, mechanical, or electronic. Where a copy of the record must be made to provide access to the record, e.g., computer printout where no screen reading is available, the copy shall be made available to the individual without cost. Where a medical record is made available to a representative designated by the individual under §21.33, no fee will be charged.

(b) The fee schedule is as follows:

(1) Copying of records susceptible to photocopying—\$.10 per page.

(2) Copying of records not susceptible to photocopying, e.g., punch cards or magnetic tapes—at actual cost to the determined on a case-by-case basis.

(3) No charge will be made if the total amount of copying for an individual does not exceed \$25.

(c) When a fee is to be assessed, the individual shall be notified prior to the processing of the copies, and be given an opportunity to amend his request. Payment shall be made by check or money order made payable to the "Food and Drug Administration," and shall be sent to the Accounting Branch (HFA-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Advance deposit shall be required where the total amount exceeds \$50.

[42 FR 15626, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989]

Subpart E—Procedures for Requests for Amendment of Records

§21.50 Procedures for submitting requests for amendment of records.

(a) An individual who received access to a record about himself under subpart D of this part may request that the record be amended if he believes that the record or an item of information is not accurate, relevant to a Food and Drug Administration purpose, timely, or complete.

(b) Amendments under this subpart shall not violate existing statute, regulation, or administrative procedure.

(1) This subpart does not permit alteration of evidence presented in the course of judicial proceedings or Food and Drug Administration adjudicatory or rule making proceedings or collateral attack upon that which has al-

ready been the subject of any such proceedings.

(2) If the accuracy, relevancy, timeliness, or completeness of the records may be contested in any other pending or imminent agency proceeding, the Food and Drug Administration may refer the individual to the other proceeding as the appropriate means to obtain relief. If the accuracy, relevance, timeliness, or completeness of a record is, or has been, an issue in another agency proceeding, the request under this section shall be disposed of in accordance with the decision in the other proceeding, absent unusual circumstances.

(c) Requests to amend records shall be submitted, in writing, to the FDA Privacy Act Coordinator in accordance with §21.40(b). Such requests shall include information sufficient to enable the Food and Drug Administration to locate the record, a brief description of the items of information requested to be amended, and the reasons why the record should be amended together with any appropriate documentation or arguments in support of the requested amendment. An edited copy of the record showing the described amendment may be included. Verification of identity should be provided in accordance with §21.44.

(d) Written acknowledgement of the receipt of a request to amend a record shall be provided within 10 working days to the individual who requested the amendment. Such acknowledgement may request any additional information needed to verify identity or make a determination. No acknowledgement need be made if the request can be reviewed, processed, and the individual notified of the agency's agreement with the request or refusal within the 10-day period.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8459, Jan. 27, 1981]

§21.51 Responses to requests for amendment of records.

(a) The Food and Drug Administration shall take one of the following actions on a request for amendment of records as promptly as possible:

(1) Amend any portion of the record which the agency has determined,